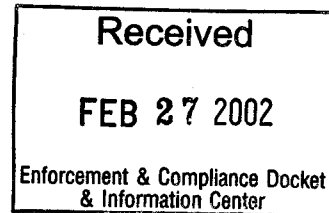


EC-2000-007
IV-D-068

February 26, 2002

United States Environmental Protection Agency
Enforcement and Compliance Docket and Information Center
Mail Code 2201A
Docket Number EC-2000-007
1200 Pennsylvania Avenue, NW
Washington, DC, 20460



RE: Establishment of Electronic Reporting: Electronic Records; Proposed Rule
(66 FR 46162)

The IPC - Association Connecting Electronic Industries - is pleased to submit the following comments in response to the Environmental Protection Agency's (EPA's) Notice of Proposed Rulemaking (NPRM) on Electronic Records published in the Federal Register at 66 FR 46162. IPC is the national trade association for the electronic interconnection industry, and represents more than 2600 member companies who manufacture printed wiring boards (PWBs) and attach electronic components, such as computer chips, to bare boards which are called printed wiring assemblies (PWAs).

PWBs and PWAs are used in a variety of electronic devices that include computers, cell phones, pacemakers, and sophisticated missile defense systems. The industry is vital to the U.S. economy. Without PWBs, you would not be able to start your car, watch television, answer a telephone, turn on a light switch, or brew a cup of coffee. There would be no Internet, no e-mail, no VCRs or Nintendo. The industry employs more than 400,000 people and exceeds \$44 billion in sales. Industry members operate in every U.S. state and territory.

Although IPC members include electronic giants, such as Intel, Hewlett Packard, and IBM, the vast majority of IPC members meet the Small Business Administration's definition of "small business." Ninety percent of IPC members, who manufacture PWBs, have sales less than \$10 million; of those, 90% have sales less than \$5 million. The typical IPC member has 100 employees on average and has a profit margin of less than four percent.

IPC members utilize sophisticated environmental management systems to continually collect varying types of environmental data for compliance with EPA programs, such as TRI reporting, RCRA waste management, wastewater permits, and air permits. If implemented, the proposed rule would have a significant impact on all of our member companies.

The IPC recommends that the Cross-Media Electronic Reporting and Recordkeeping Rule (CROMERRR) proposal be withdrawn. At the very least, the recordkeeping provisions should be withdrawn. IPC supports cost-effective environmental regulations that produce real environmental benefits. However, we oppose EPA's proposed CROMERRR since the rule is expensive and overly burdensome without producing a benefit to the environment or the regulated community. In fact, CROMERRR fails to achieve its intended goal of reducing the burden of compliance while actually adding to the problem. As written the proposal:

- Appears to broadly regulate the use of computers to collect, store, and process environmental data, going far beyond its ostensible voluntary nature,

- Prohibits current practices using data stored on computers to meet EPA recordkeeping requirements,
- Requires very expensive retrofits for existing computer systems or the purchase of new computer systems, and
- Endorses a “one size fits all” approach to electronic recordkeeping, while failing to conduct OMB suggested risk assessments or cost-benefit analysis on the need for such stringent anti-fraud provisions.

IPC appreciates the opportunity to comment on the agency's proposed rule. Each of our concerns is discussed in further detail below.

I. CROMERRR's Recordkeeping Provisions Would Be Mandatory

The agency's proposal portrays the recordkeeping provisions as voluntary stating that, “Under today's proposal, electronic document submission or electronic recordkeeping will be totally voluntary,”^{<1>} and that “It was also assumed that a very low number of facilities (0.5 percent) of the current regulated entities, would elect to acquire new electronic recordkeeping systems to implement the CROMERRR recordkeeping option.”^{<2>}

Notwithstanding such statements, the language of CROMERRR as proposed would be mandatory for most records kept electronically in order to meet EPA requirements.^{<3>} The

“any combination of text, graphics, data, audio, pictorial, or other information represented in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system,”^{<4>}

would encompass both records kept electronically at all times and those created or stored temporarily on a computer. Specifically, the rule's text confuses electronic records and data by considering all data stored in a computer as an electronic record. This causes serious concern for the PWB industry since manufacturing processes use computer systems to compile large amounts of data that would be considered electronic records as defined by the proposal, mandating that facilities comply with CROMERRR provisions. We recommend that the agency clarify the difference between records and data and furthermore, make clear those that are intended to be covered by this rule.

Once qualifying as an “electronic record,” information kept electronically to meet EPA recordkeeping requirements would be subject to the provisions of Subpart C of proposed Part 3, requiring substantial investment to retrofit current computer systems. Proposed § 3.100(a) would provide in part that:

“An electronic record . . . will satisfy a recordkeeping requirement of an EPA-administered environmental program under this Title [i.e., 40 CFR] only if it is generated and maintained by an acceptable electronic record-retention system as specified under this subsection.”^{<5>}

Where regulated entities routinely store monitoring data, emissions data, or other information on

a computer, such storage would apparently subject the regulated entities to all CROMERRR requirements for electronic recordkeeping, in contrast to the proposals "voluntary" description.

Analysis of the Federal Drug Administration's (FDA's) implementation of rule 21 CFR Part 11, which directly corresponds to CROMERRR, illustrates the scope EPA intends for the proposed electronic recordkeeping rule. EPA specifically stated that its proposed CROMERRR provisions "are intended to be consistent with criteria set forth for electronic document systems in other relevant regulations, such as FDA's criteria in 21 CFR part 11."⁶ A comparison of CROMERRR and 21 CFR Part 11 shows that EPA closely modeled CROMERRR on the earlier FDA rule.

The definition of "electronic record"⁷ under the FDA rule, issued in 1997,⁸ is virtually identical to the corresponding definition in CROMERRR. Like the CROMERRR proposal, the FDA rule declared that the recordkeeping provisions were voluntary, stating, "The use of electronic records as well as their submission to FDA is voluntary."⁹

However, as implemented, the apparent voluntary nature of the FDA rule made any agency-mandated records that are generated or maintained electronically at any point in their lifetimes subject to the regulation. Since it is very difficult to escape the use of "electronic records" as interpreted by the FDA, CROMERRR could be considered mandatory for all EPA-required records that are at some point electronic, suggesting that recordkeeping requirements are in fact not "voluntary".

Accordingly, CROMERRR is not "voluntary" at all. In today's electronic age, most regulated entities would have no choice but to collect and store data on a computer, and that seems to be enough to subject facilities to CROMERRR recordkeeping provisions. The result would be that all or most entities subject to EPA recordkeeping requirements would have to adapt their computer systems to meet CROMERRR requirements.

II. CROMERRR Would Prohibit Current Use of Computers to Keep EPA-Mandated Records.

The CROMERRR proposal indicates that EPA will inform regulated entities when they may begin to keep mandated records on a computer stating:

"Any regulated company or other entity that maintains records addressed by today's proposal . . . under EPA regulations can store them in an electronic form subject to the proposed criteria for electronic recordkeeping as soon as EPA announces that the specified records may be kept electronically."¹⁰

This language suggests that current practices that employ computers to store EPA-required records are impermissible, since EPA has not yet made an announcement permitting such practices. While EPA may not have intended this result, the proposal's language suggests that all current electronic recordkeeping unacceptable for meeting EPA recordkeeping requirements.

III. CROMERRR Recordkeeping Requirements Impose A Substantial Financial Burden on Businesses.

The CROMERRR economic analysis declares that the cost of complying with the recordkeeping provisions would be approximately \$40,000 per facility.^{<11>} Experience with FDA's 21 CFR Part 11, counterpart to CROMERRR, suggests that this may be a considerable underestimate of the costs, which would seem likely to reach into the millions of dollars per regulated entity.

Furthermore, facilities not wishing to participate in electronic reporting may be required to do so under the currently broad definition of "electronic record" creating an unwanted cost burden in order to retrofit computer systems.

It should be noted that FDA similarly estimated that its rule would have little financial impact, yet the pharmaceutical industry has been required to make substantial investments to come into compliance with 21 CFR Part 11.

Every regulated entity subject to CROMERRR would be obligated to purchase thousands to millions of dollars of add-ons to existing systems and/or purchase new computer systems. Few of these costs are apparent from reading the CROMERRR proposal, but the experience of the pharmaceutical industry in attempting to comply with 21 CFR Part 11 suggests that CROMERRR may carry very substantial costs.

IV. EPA Failed to Conduct a Risk Assessment and Cost-Benefit Analysis on the Need for Stringent Anti-Fraud Provisions in CROMERRR, Instead Choosing a "One Size Fits All" Approach.

CROMERRR is EPA's response to the Government Paperwork Elimination Act ("GPEA").^{<12>} The GPEA directs the Office of Management and Budget (OMB) to issue guidance to Executive Branch agencies on GPEA implementation. OMB issued guidance to EPA^{<13>} stating that:

"?. Agencies should develop and implement plans, supported by an assessment of whether to use and accept documents in electronic form and to engage in electronic transactions. The assessment should weigh costs and benefits and involve an appropriate risk analysis, recognizing that low-risk information processes may need only minimal consideration, while high-risk processes may need extensive analysis."^{<14>}

EPA apparently did not conduct either a risk assessment or cost-benefit analysis. Instead, the agency seems to have concluded that there was a high need for rigorous provisions to deter or punish fraud in connection with all EPA-mandated recordkeeping requirements.

CROMERRR imposes substantial anti-fraud provisions that most current computer systems simply do not have. These requirements apply both to new systems and to existing systems. There would apparently be no grandfathering of legacy systems under CROMERRR, as there is none under Part 11. As FDA explained:

"The agency believes that . . . a general exemption for existing systems that do not meet these provisions would be inappropriate and not in the public interest . . ."^{<15>}

"As explained in the preamble to the final rule, Part 11 does not grandfather legacy systems and

FDA expects that firms using legacy systems will begin taking steps to achieve full compliance.”
<16>

CROMERRR anti-fraud provisions would be in addition to existing anti-fraud provisions. The federal criminal code already prohibits making a false statement to the government or keeping fraudulent records required by the government.<17> Most or all EPA-administered statutes contain specific prohibitions on making false statements or keeping false records.<18> Instead, following FDA's example, EPA prescribed a “one size fits all” approach to CROMERRR, apparently assuming that all EPA-mandated records, regardless of their nature, have the highest level of sensitivity.

The OMB guidance further suggests that if EPA had conducted a risk assessment and cost-benefit analysis, it might have found that its concerns with fraud in electronic recordkeeping were excessive:

“Setting up a very secure, but expensive, automated system may in fact buy only a marginal benefit of deterrence or risk reduction over other alternatives and may not be worth the extra cost. For example, past experience with fraud risks, and a careful analysis of those risks, shows that exposure is often low. If this is the case, a less expensive system that substantially deters fraud is warranted, and not an absolutely secure system. Overall, security determination should conform with the Computer Security Act: the level of security should be commensurate with the level of sensitivity of the transaction.”<19>

In particular, the OMB guidance advises that the risk of fraud is lowest where there is an ongoing relationship, as with EPA and regulated entities:

“Risks tend to be relatively low in cases where there is an ongoing relationship between the parties. Generally speaking . . . transactions between a regulatory agency and a publicly traded corporation or other known entity regulated by that agency can often bear a relatively low risk of repudiation or fraud, particularly where the regulatory agency has an ongoing relationship with, and enforcement authority over, the entity.”<20>

EPA keeps careful track of its regulated entities, routinely inspects them, and deals with them on an ongoing basis. Accordingly, the risk of fraud is probably quite low.

In contrast to EPA and FDA, other federal agencies implementing the GPEA have chosen to adjust the degree of anti-fraud protections to the risk of fraud and the consequences of fraud. For example, the Treasury Department has adopted policies and practices for the use of electronic transactions and authentication techniques in federal payments and collections.<21> It uses a risk-based approach that, “All payment, collection, and collateral transactions must be properly authenticated, in a manner commensurate with the risks of the transaction.”<22> Transactions with negligible risk may occur without any electronic authentication technique. Those with low risk must use a single factor authentication, such as a personal identification number. Those with moderate or high risk would require more in the way of authentication, such as cryptography.

The actions of other agencies suggest that EPA can address the deterrence and detection of fraud in recordkeeping requirements in a risk-based manner. There is no indication in CROMERRR that EPA has done so.

V. Conclusion

In summary, IPC opposes the proposed rule given that CROMERRR recordkeeping provisions, while portrayed as voluntary, would be mandatory for almost all entities using computers to store data intended to meet EPA recordkeeping requirements. This would necessitate expensive upgrades for current computer systems, creating a substantial financial burden on regulated entities. Furthermore, CROMERRR would prohibit the current use of electronic means to store data intended to meet EPA recordkeeping requirements until otherwise specified by EPA, severely impacting existing business practices. Lastly, IPC questions the "one size fits all" approach to electronic recordkeeping prescribed by EPA while the agency fails to conduct a risk assessment or cost/benefit analysis of the need for CROMERRR's stringent anti-fraud provisions.

While electronic recordkeeping and reporting has the potential to reduce paperwork making reporting requirements more efficient and less burdensome for regulated entities, the proposed rule fails to accomplish this objective. CROMERRR is an extremely costly and arduous regulation that provides no real benefit to environment or industry.

We appreciate the opportunity to comment of EPA's proposed CROMERRR and look forward to working with the agency to develop electronic reporting and recordkeeping options that are beneficial to the nation's economic and environmental health. Please contact us with any questions at (202) 962-0464, or by email at fabrams@ipc.org.

Sincerely,

Fern Abrams
Director of Environmental Policy

1 66 Fed. Reg. 46162 (Aug. 31, 2001).

2 66 Fed. Reg. at 46178.

3 There is an exception for hazardous waste manifest documentation kept electronically. See 66 Fed. Reg. at 46163. EPA published a proposed rule on electronic hazardous waste manifests at 66 Fed. Reg. 28240, (May 22, 2001). This working paper does not address that proposed rule.

4 66 Fed. Reg. at 46189.

5 66 Fed. Reg. at 46190 (emphasis added).

6 66 Fed. Reg. at 46170.

7 21 CFR § 11.3(b)(6).

8 62 Fed. Reg. 13430 (Mar. 20, 1997).

9 62 Fed. Reg. at 13430.

10 66 Fed. Reg. at 46167 (emphasis added).

11 66 Fed. Reg. at 46178.

12 Pub. L. No. 105-277, Title XVII (Oct. 21, 1998).

13 65 Fed. Reg. 25508 (May 2, 2000).

14 65 Fed. Reg. at 25513.

15 62 Fed. Reg. at 13434.

16 64 Fed. Reg. 39146, 39147 (July 21, 1999).

17 18 U.S.C. § 1001.

18 See, e.g., TSCA § 16(b), 15 U.S.C. § 2615(b); FIFRA §§ 12(a)(2)(M), (Q), (R), 7 U.S.C. §§ 136j(a)(2)(M), (Q), (R).

19 65 Fed. Reg. at 25515 (emphasis added).

20 65 Fed. Reg. at 25517 (emphasis added).

21 66 Fed. Reg. 394 (Jan. 3, 2001).

22 66 Fed. Reg. at 396.



Sonya Walter
<swalter@ipc.org>

02/26/02 05:47 PM

Please respond to
swalter

To: docket.oeca@epamail.epa.gov
CC:
Subject: EC-2000-007

Attached please find a copy of IPC's comments on Establishment of Electronic Reporting: Electronic Records Proposed Rule (66 FR 46162).

IPC appreciates the opportunity to comment on the agency's proposed rule.

Thank you,
Sonya Walter

1333 H Street, NW
11th Floor West
Washington, DC 20005
(202) 962-04600



CROMERRR.doc

